Preferred Drug List Committee Meeting

Meeting Minutes, Open Session
September 11, 2019 11:30 a.m. to 1:00 p.m.
DXC Technologies-Capital Room, 6511 SE Forbes Ave., Bldg. 283 J, Topeka, Kansas 66619

Board Members Present:

Jessica Bates, Pharm.D., BCPS (Chair)	William Pankey, M.D
Emily Blew, Pharm.D. (Phone)	James Rider, D.O. (Phone)
Katherine Grimsley, M.D.	Donna Sweet, M.D. (Phone)
Megan Hedden, Pharm.D.	Wayne Wallace, M.D.
Robert Haneke, Pharm.D. (Phone)	Taylor Gill, Pharm.D., BCPS, (Phone)

KDHE-DHCF Staff Present:

Annette Grant, RPh
Victor Nguyen, Pharm.D.
John Esslinger, M.D.
Margaret O'Donnell, Transcriptionist

DXC/HID Staff Present:

Karen Kluczykowski, RPh
Kathy Kaesewurm, RN, BSN

Public Attendees:

Dawn Lease, Johnson&Johnson; Brent Hildebrand, Gilead; Laura Hill, Melissa Basil, Abbvie; Adam Wilson, KDHE pharmacy intern; Jason Tessmer, Novo Nordisk; Jomy Joseph, Dana Koehn, Sanofi; Carl Peterson, KU; Randy McGinley, Bayer; Nick Boyer, Xeris; Jim Baumann, Rob Hansen, Pfizer; Megan Kerrigan, Merck;

Item	Notes
I. Call to Order	Dr. Bates called the September 11, 2019 PDL Committee meeting to order at 11:32 a.m. Dr. Bates addressed the board members present and attending by phone.
II. Review and Approval of June 12, 2019 Meeting Minutes.	The draft minutes from the June 12, 2019 meeting were reviewed. Ms. Grant informed the Board that Dr. Rider's credentials were listed incorrectly and have been updated. Dr. Sweet moved to approve the minutes. Dr. Wallace seconded the motion. The motion carried unanimously, and the minutes were approved.
III. Old Business **A. Consent Agenda Items** **i. PDL New Drug Placements** 1. Cortisporin®TC 2. Katerzia™ 3. Humulin® R U-500 4. Saizen® Click.Easy 5. Saizenprep®	**Background:** At the September 13, 2017 PDL meeting, the Committee agreed to the "Consent Agenda Items" pre-management process and to place the associated drug list under the Old Business section. Approved items will be in Appendix A of the minutes. **Public Comment:** None. **Board Discussion:** Dr. Sweet moved to approve. Dr. Wallace seconded the motion. The motion carried unanimously.
IV. New Business **A. Acne Agents – Tetracyclines –Oral-New Class: (Acticlate®, Avidoxy, CoreMino, Demeclocycline, Doryx®, Doryx® MPC, Doxycycline, Dynacin®, Minocin®, Minocycline, Minolira™, Monodox®, Morgidox®, Seysara™, Solodyn®, Targadox®, Tetracycline, Vibramycin®, Ximino)**	**Background:** The oral, tetracycline agents used to treat acne are being presented today for approval and inclusion to the PDL. Well-known agent, Sumycin® was FDA approved in 1954 and the most recent tetracycline, Seysara™, was approved in October 2018. These agents are bacteriostatic and act by inhibiting protein synthesis. Tetracyclines have a wide spectrum of antimicrobial activity against both gram-negative and gram-positive organisms, particularly Cutibacterium acnes. These drugs penetrate the follicle and sebaceous glands well and decrease bacterial colonization. **Public Comment:** None.

Item	Notes
	Committee Discussion: There was a question on how this will affect the PA list. The State replied that it is the same as all other PDL classes where preferred drugs do not require a PDL PA and non-preferred do require a PDL PA. Dr. Wallace moved to approve. Dr. Rider seconded the motion. The motion carried unanimously.
B. Skin and Skin Structure Agents – Tetracyclines – Oral – New Class: (Avidoxy, Demeclocycline, Dynacin®, Minocin®, Minocycline, Nuzyra™, Tetracycline)	**Background:** The oral, tetracycline agents used to treat skin and skin structure infections are being presented today for approval and inclusion to the PDL. One of the first agents, Minocin®, was first approved in 1971 and most recently, a new agent, Nuzyra™, was approved in October 2018. These antibiotics are bacteriostatic and act by inhibiting protein synthesis. These drugs penetrate the skin tissue well and have a broad spectrum of antimicrobial activity. **Public Comment:** None.
B. Skin and Skin Structure Agents – (Continued)	**Committee Discussion:** There were questions about whether the drugs in these two classes should be the same. The State responded that the bottom ones were specifically for skin and skin structure infection. *Labeling by indication as well as drug class to make sure those other indications get access right away. There were questions about whether the indications are included when the prescriptions are processed. The State responded that they are not. Even if the prescription has to go through a PA, the patient's already going to be started on a first-line drug. The indication comes in through the PA process. Dr. Wallace moved to approve. Dr. Pankey seconded the motion. The motion carried unanimously.

Item	Notes
C. Request to rename Immunomodulation Agents – Topical to Atopic Dermatitis Agents - Topical	**Background:** Request to rename Immunomodulation Agents – Topical to Atopic Dermatitis Agents – Topical **Public Comment:** None. **Committee Discussion:** The State commented that the reasons for this change are that Eucrisa® is a Phosphodiesterase-4 Enzyme Inhibitor and also that they are trying to align the PDL and PA programs, where possible. Dr. Sweet moved to approve Dr. Rider seconded the motion. The motion carried unanimously
D. Hemophilia A Factor VIII Agents – Long Acting – Prophylaxis Use-New Class: Adynovate®, Eloctate®, Esperoct®, Jivi®)	**Background:** The long acting, hemophilia A factor VIII agents for prophylactic use are being presented today for approval and inclusion to the PDL. These agents can be given periodically to temporarily replace the missing plasma factor VIII and reduce the number of bleeding episodes in adults and adolescents with hemophilia A. Esperoct® was most recently approved by the FDA in February 2019 and is not yet available on the market. **Public Comment:** None. **Committee Discussion:** Dr. Wallace moved to approve.

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	Dr. Sweet seconded the motion. The motion carried unanimously.
E. Hemophilia B Factor IX Agents – Long Acting – Prophylaxis Use-New Class: (Alprolix®, Idelvion®)	**Background:** The long acting, hemophilia B factor IX agents for prophylactic use are being presented today for approval and inclusion to the PDL. Factor IX Fc fusion protein recombinant temporarily replaces the missing coagulation Factor IX needed for effective hemostasis. These agents will help prevent bleeding episodes in patients with hemophilia B when used prophylactically. **Public Comment:** None. **Committee Discussion:** Dr. Hedden moved to approve. Dr. Wallace seconded the motion. The motion carried unanimously
V. Open Public Comment	Ms. Grant announced that moving forward, the State has decided to have Biannual PDL meetings versus quarterly. Ms. Grant used the remaining time to speak to the committee about previous questions they have had. She welcomed questions, concerns, or suggestions via E-mail and will then bring them up at future meetings.
VI. Adjourn	Dr. Wallace moved to adjourn. Dr. Rider seconded the motion. Dr. Bates adjourned the meeting at 12:17 p.m.

APPENDIX A

September 2019 Consent Agenda Item List				
This PDL option/process was approved 09/13/2017 by the PDL Committee and 10/11/2017 by the DUR Board. The Extended Consent Agenda was approved at the March 2019 PDL Committee meeting and the April 2019 DUR Board meeting.				
Drug Proposed - Consent Agenda Item	**Compare Drug**	**Supporting information**	**Meeting Date listed on the PDL Agenda**	**PDL Committee Approval Yes/No**
Cortisporin® TC		Was DC'd & now available again.	9/11/2019	**Yes - 2019-09-11**
Katerzia™	Norvasc		9/11/2019	**Yes - 2019-09-11**
Humulin® R U-500	Humulin® R U-100		9/11/2019	**Yes - 2019-09-11**
Saizen® Click Easy	Saizen®		9/11/2019	**Yes - 2019-09-11**
Saizenprep®	Saizen®		9/11/2019	**Yes - 2019-09-11**